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10/525,385	02/23/2005	Akihisa Takaichi	Q86331	4927
23373 7590 02/20/2009 SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037				
EXAMINER				
GWARTNEY, ELIZABETH A				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/525,385

**Applicant(s)**

TAKAICHI ET AL.

**Examiner**

Elizabeth Gwartney

**Art Unit**

1794

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 November 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SG/US)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Response to Amendment***

1. The Amendment filed 11/24/2008 has been entered. Claims 5-6 have been added.

Claims 1-6 are pending.

***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 recites "guar gum or gellan gum, 0.05-0.3 wt%." While the specification describes a composition wherein the proportion of guar gum or gellan gum in the gel composition of the invention is *about* 0.05 to *about* 0.3%, there is no support in the specification for 0.05-0.3%.

***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
  2. Ascertaining the differences between the prior art and the claims at issue.
  3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
5. Claims 1 and 3-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fuchs et al. (WO 01/01789) in view of Emoto (US 6,458,395).

Regarding claim 1, Fuchs et al. disclose a gel composition comprising the following components and having a pH in the range of 3.5 to 4.1 (Abstract, P6/L1-2):

- Protein or its hydrolysate	2-4.5 wt% (P8/Table)
-Calcium	0.02-0.270 wt% (P5/Table)
-Acidulant	(P6/L2-5)
-Carbohydrate	11-20 wt% (P8/Table)

-Fat	(P4/L22-23 – lipid source optional)
-Water	~ 72-80 wt% (P6 – based on a solids content of 20-28% by weight)

Fuchs et al. does not explicitly disclose that the protein does not coagulate at pH 3 to pH 4 , a gel composition comprising agar and a gum including gellan gum or guar gum or that the acidulant is present in an amount of 0.5 -3 wt%.

Regarding coagulation, since the protein, whey protein isolate, disclosed by Fuchs is identical to that presently claimed, it is clear that it would intrinsically display the coagulation properties recited in the present claim.

Regarding acidulant, given that Fuchs et al. disclose a composition including acidulant and a pH identical to that presently claimed, it is clear that the amount of acidulant would inherently be in the range presently claimed.

Regarding gelling agents, Emoto teaches a nutritionally balanced gelatinous food product which is a composite gel formed with protein and about 0.2 to 5% of a gelling agent such as agar, guar gum or a combination thereof (Abstract, C5/L24-25). Emoto teaches that gelling agents have gelling and gel-stabilizing ability (C5/L26-28).

Fuchs et al. and Emoto are combinable because they are concerned with the same field of endeavor, namely, nutritionally supplemented protein gels. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have added about a combination of agar and guar gum, as taught by Emoto, to the gel composition of Fuchs et al. to provide gel strength and stability to the gelatinous food product.

While Emoto teaches the addition of about 0.2 to about 5% of an agar and guar gum gelling agent combination, the reference does not explicitly disclose 0.1 to 1.0% agar and 0.05 to 0.3% guar gum. As gel texture is a variable that can be modified, among others, by adjusting the ratio of gelling agents, the precise concentration of agar and guar gum in the gelling agent combination would have been considered a result effective variable by one of ordinary skill in the art at the time of the invention. As such, without showing unexpected results, the claimed concentration of agar and guar gum in the gelling agent combination cannot be considered critical. Accordingly, one of ordinary skill in the art at the time the invention was made would have optimized, by routine experimentation, the concentration of agar and guar gum in the gelling agent combination of modified Fuchs et al. to obtain the desired texture characteristics (*In re Boesch*, 617 F.2d. 272, 205 USPQ 215 (CCPA 1980)), since it has been held that where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. (*In re Aller*, 105 USPQ 223).

Regarding claim 3, Fuchs et al. disclose all of the claim limitations as set forth above. Further, Fuchs et al. disclose a gel composition further vitamin D in an amount of  $0.25 \times 10^{-6}$  to  $0.625 \times 10^{-6}$  wt% (P5/Table – where 1 IU of vitamin D = 0.025 µg).

Regarding claim 4, Fuchs et al. disclose all of the claim limitations as set forth above and that the protein is whey protein isolate (P3/L18-25, P8/Table). Since the protein disclosed by Fuchs is identical to that presently claimed, it is clear that it would intrinsically display the coagulation properties recited in the present claim.

6. Claims 2 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fuchs et al. (WO 01/01789) in view of Emoto (US 6,458,395) as applied to claim 1, and further in view of Ohkuma et al. (US 5,364,652).

Regarding claims 2 and 6, modified Fuchs et al. disclose all of the claim limitations as set forth above. While Fuchs et al. disclose a gel composition comprising 5-50 wt% fruit juice (P8/Table), the reference does not disclose a gel composition comprising 0.1 to 20 wt% of at least one masking agent selected from the group consisting of hard-to-digest dextrin, reduced hard-to-digest dextrin, nigerooligosaccharide and trehalose.

Ohkuma et al. teach food products comprising about 3.3% to about 52.5 % indigestible dextrin (Abstract, Examples 5-53) and that indigestible dextrin is a good source of dietary fiber (C1/L65-C2/L15). Ohkuma et al. teach that indigestible substances in the diet contribute to gastrointestinal health and reduced cholesterol (C2/L58-68).

Modified Fuchs et al. and Ohkuma et al. are combinable because they are concerned with the same field of endeavor, namely food products for nutritional supplementation. It would have been obvious to one of ordinary skill in the art at the time of the invention to have included indigestible dextrin, as taught by Ohkuma et al., in the gel composition of modified Fuchs et al. for the purpose of making a product which contributes to gastrointestinal health and reduced cholesterol.

7. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fuchs et al. (WO 01/01789) in view of Emoto (US 6,458,395) as applied to claim 1, and further in view of Morris et al. (US 5,869,118).

Regarding claim 5, modified Fuchs et al. disclose all of the claim limitations as set forth above. While modified Fuchs et al. disclose a gel composition comprising a gelling agent combination of agar and guar gum, the references do not explicitly disclose gellan gum.

Morris et al. teach a liquid nutritional composition comprising 10 to 500 ppm gellan gum (0.001% to 0.05%) (Abstract, C4/L56-60). Morris et al. teach that the utilization of low concentrations of gellan gum results in the formation of a weak three dimensional network that effectively holds ingredients such as calcium, insoluble fiber and insoluble flavoring agents (C4/L24-38, C7/L22-29, Abstract). Morris et al. teach that gellan gum improves the physical stability of protein based nutritional compositions (C3/L60-67).

Modified Fuchs et al. and Morris et al. are combinable because they are concerned with the same field of endeavor, namely, protein-based nutritional products. It would have been obvious to one of ordinary skill in the art at the time of the invention to have included gellan gum, as taught by Morris et al., in the gel composition of modified Fuchs et al. for the purpose of improving the physical stability of insoluble components.

### ***Double Patenting***

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting



ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 3-5 are provisionally rejected on the ground of nonstatutory double patenting over claims 1-7 of copending Application No. 10/521,170. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

Although the copending claims are drawn to a gel beverage composition while the present claims are drawn to a gel composition for protein and calcium supplementation, there is clear overlap between the present claims and the copending claims. Specifically, US appl. '170 claims a gel beverage composition having a pH of 3-4 and comprising protein which does not coagulate at pH 3-4, agar, water, acidulant, fat, and saccharide. Further, US appl. '170 claims a protein material which does not coagulate at pH 3-4 selected from the group consisting of protein hydrolysate having a number average molecular weight of 500-10000, whey protein concentrate, whey protein isolate and desalted whey. US appl. '170 also claims a gel composition containing a gelling agent selected from the group consisting of gellan gum, carrageenan, pectin and gelatin.

US appl. '170 does not teach a gel composition comprising 0.1-0.5 wt% calcium, 0.1 X  $10^{-6}$  to 10 X  $10^{-6}$  wt % vitamin D, or 0.1 to 20 wt% masking agent.

Fuchs et al. (WO 01/01789) teach a gel composition comprising 0.02 – 0.270 wt% calcium (P5/Table), 0.25 X  $10^{-6}$  to 0.625 X  $10^{-6}$  wt% vitamin D (P5/Table – where 1 IU of vitamin D = 0.025  $\mu$ g) and 5-50 wt% fruit juice. Fuchs et al. teach that calcium and vitamin D are added to supplement the nutritional profile of the gel composition. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have added

calcium, vitamin D and fruit juice, as taught by Fuchs et al., to the gel composition of US appl. '170 for the purpose of improving the nutritional and flavor quality of the gel composition.

Claims 1 and 3-5 directed to an invention not patentably distinct from claims 1-7 of commonly assigned US appl. '170. Specifically, although the conflicting claims are not identical, they are not patentably distinct for the reasons set forth above.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned 10/521,170, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

#### ***Response to Arguments***

9. Applicant's arguments, see page 6, filed 02/20/2008, with respect to **Double Patenting** have been fully considered and are persuasive. The provisional rejection of claims 1-4 under 35

U.S.C. 103(a) has been withdrawn. However, given that applicants have deferred response to the obviousness-type double patenting rejection, the rejection has been maintained.

10. Applicant's arguments filed 11/24/2008 regarding claims 1-4 have been fully considered but they are not persuasive.

Applicants explain that the composition of the present invention contains protein and calcium in high concentrations, but has a refreshing taste and is in the form of a soft gel suitable for eating and drinking. Applicants argue that the cited references do not teach or suggest the features of the present invention.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., refreshing taste and soft gel suitable for eating and drinking) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Further, applicants have failed to show that the gel composition of modified Fuchs would not display the taste and textural properties of the present invention. Because there is substantial evidence to support determination of a prima facie case of obviousness over each of the applied prior art references, the burden of proof was properly shifted to the applicants to rebut the prima facie case by presenting persuasive arguments or evidence (e.g. unexpected results). *In re Mayne*, 104 F.3d 1339, 1343, 41 USPQ2d 1451, 1455 (Fed. Cir. 1997). ("With a factual foundation for its prima facie case of obviousness shown, the burden shifts to applicants to

demonstrate that their claimed fusion proteins possess an unexpected property over the prior art.")

Unexpected results must be established by factual evidence; mere argument or conclusory statements in the specification do not suffice. *In re Geisler*, 116 F.3d 1465, 1470, 43 USPQ2d 1362, 1365 (Fed. Cir. 1977) (quoting *In re De Blauwe*, 736 F.2d 699, 705, 222 USPQ 191, 196 (Fed. Cir. 1984)). Unexpected results must be established by comparing the claimed invention against the closest prior art. *In re De Blauwe*, 736 F.2d 699, 705, 222 USPQ 191, 196 (Fed. Cir. 1984) ("[A]n applicant relying on comparative tests to rebut a prima facie case of obviousness must compare his claimed invention to the closest prior art."); accord *In re Merchant*, 575 F.2d 865, 869, 197 USPQ 785, 788 (CCPA 1978).

Applicants explain that Fuchs et al. already employs gelled protein to obtain a gelling composition. Applicants argue that a person skilled in the art would not further add gelling agents to the composition, even in view of Emoto.

It is the Examiner's position, given that Emoto teaches a protein gel composition substantially similar to Fuchs et al., one of ordinary skill in the art would have applied the teachings of Emoto, including the addition of gelling agents, to improve gel strength and water-releasability so that the gel could be crushed easily in the mouth with the tongue (C5/L22-31).

Applicants argue that there is no apparent reason to specifically select agar among the gelling agent of Emoto. Further, applicants argue that the combination of agar and guar gum or gellan gum is not obvious.

While Emoto does not teach a specific combination of gelling agents, given that Emoto discloses a gel composition comprising a gelling agent including pectin, furcelleran, carrageenan,

agar, locust bean gum, guar gum and arabic gum, used singly or in combination, it would have been obvious to one of ordinary skill in the art to have tried each gelling agent singly and in combination in the gel composition of Fuchs et al., and arrive at the current invention.

Applicants explain that when using cation-reactive gelling agents such as gellan gum and carrageenan, it is difficult to gelate compositions containing high concentrations of protein and calcium. Applicants argue that there is no teaching or suggestion in Emoto regarding suitable gelling agents for compositions containing high concentrations of protein and calcium.

While Emoto does not explicitly teach that the gelling agent are suitable for compositions containing high concentrations of protein and calcium, given that Emoto teaches gelling agents identical to those presently claimed, it is clear that they would intrinsically be suitable for gel composition containing high concentrations of protein and calcium.

### ***Conclusion***

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Gwartney whose telephone number is (571) 270-3874. The examiner can normally be reached on Monday - Thursday; 7:30AM - 5:00PM EST, working alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Callie Shosho can be reached on (571) 272-1123. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. G./

Examiner, Art Unit 1794

/Callie E. Shosho/  
Supervisory Patent Examiner, Art Unit 1794

